

REMARKS

In the amendments above, Claim 37 has been amended, and Claim 44 has been cancelled, to more particularly point out and distinctly claim Applicants' invention.

In the Office Action, the Examiner commented about the priority of the above application. The Examiner's attention is directed to the amendments above, where reference to the corresponding U.S. provisional patent application has been inserted, consistent with papers submitted earlier.

Response to Rejections under 35 U.S.C. § 102

Claims 37-39, 41-43, and 45-50 have been rejected under 35 U.S.C. § 102(e). The Examiner contends that these claims are anticipated by Tanner et al., U.S. Patent No. 6,635,066 ("Tanner").

Applicants respectfully traverse this rejection.

Tanner describes similarly to previously cited documents an endograft or standard graft with stent and cuffs (docking heads) that are inserted through femoral arteriotomy in both common iliacs and therefore are inserted using a guiding device. Moreover, Tanner describes a method of inserting the repairing device in at least two steps wherein in one step, the cuffs are being inserted and fastened by a special instrument/apparatus or suturing to the aneurism from within the vessel, without opening the aneurysm and only in the next step the graft is inserted and fastened to the cuffs (see, Col. 24, line 66, to Col. 25, line 67). The cuffs and the graft are being inserted as separate modules.

In contradistinction, the device of the present invention is introduced into the aneurism directly through an incision and the docking heads are adjusted along and fastened to the graft at a suitable position on the graft prior to insertion into the vessel . The graft and the docking head comprise one module at the time of insertion and aneurysm neck takes the shape of the firm docking head.

Tanner also discloses fasteners that are used to fasten the attachment device (the cuffs) to the vessel. However, the fasteners are autonomic spring elements and not barbs. The spring fasteners usually with spiral structure are connected to polymer flexible material of the cuff and to the material of the graft by suturing and do not have a firm base, which allow its inclination in certain direction (Figs. 25-36). The fastening spring elements do not puncture the blood vessel wall.

In contradistinction, the barbs of the present invention are connected to the docking head in a predetermined certain angle and are connected to firm portion of the docking head. The barbs have a sharp end, perforating the layers of the blood vessel wall.

Claim 37 specifically claims elements and features that are in contradiction to the description of Tanner:

" wherein each of the first and second docking heads is adapted to be adjusted along and fastened to the graft at a suitable position on the outer surface of the graft prior to insertion into the vessel

“ wherein a plurality of outwardly pointing barbs are connected to at least one of the docking heads wherein the barbs are flexible and are inclined towards a longitudinal direction of the graft at a predetermined angle"

Therefore, Claim 37 as amended is patentably distinct from Tanner and should be allowed, as should as well Claims 38-39, 41-43 and 45-50 that depend on Claim 37.

Response to Rejections under 35 U.S.C. § 103

Claims 37-39, 41-43 and 45-50 have been rejected under 35 U.S.C. § 103(a). The Examiner contends that these claims are unpatentable over Tanner in view of Weadock, U.S. Published Patent Application No. 2004/0225351 ("Weadock") or Baker, U.S. Published Patent Application No. 2002/0091439 ("Baker").

Applicants respectfully traverse this rejection.

Weadock as well as Baker discloses devices that are inserted to the area of the aneurism through the iliac arteries in small dimensions and are expending after placement. The staples (28) of Weadock and the wall engaging member (195) of Baker are attached to the expandable device and are randomly directed to a certain direction. The staples and the engaging member are merely supporting the connection between the graft and the vessel in contradiction to the claimed invention in which the barbs are inclined and directed in a predetermined direction in order to establish the connection between the docking head and the vessel wall.

Tanner discloses fasteners that are connected to the graft or the cuffs by the surgeon before or during the procedure and are being manually directed. Therefore, it cannot be obvious to a person skilled in the art to engage engagement members or staples that are pre-connected to the device to Tanner that uses manually engaged fasteners.

The other rejected claims are now dependent on patentable subject matter and therefore, should be also allowed.

Claims 51-53, 55-57, and 59-63 have been rejected under 35 U.S.C. § 103(a). The Examiner contends that these claims are unpatentable over Weadock in view of Tanner. Also, Claims 37-39, 41-47, and 49-50 have been rejected under 35 U.S.C. § 103(a). The Examiner contends that these claims are unpatentable over Elliot et al., U.S. Published Patent Application No.2003/0236567) in view of Weadock or Baker.

Applicants respectfully traverse these rejections.

Weadock as well as Baker discloses devices that are inserted to the area of the aneurism through the iliac arteries of small dimensions and are expending after placement. The staples (28) of Weadock and the wall engaging member (195) of Baker are attached to the expandable device and are randomly directed to a certain direction.

The staples and the engaging member are merely supporting the connection between the graft and the vessel in contradiction to the claimed invention in which the barbs are inclined and directed in a predetermined direction in order to establish the connection between the docking head and the vessel wall.

The device of Elliot, on the other hand, has no need of any connecting means that will facilitate the connection between Elliot's skirt and the vessel. Elliot, all through the description, does not imply or suggest such need. Therefore, it cannot be obvious to a person skilled in the art to engage engagement members or staples as described in Weadock or Baker, respectively, to the device of Elliot that has no need in any stapling like connection.

The other rejected claims are now dependent on patentable subject matter and therefore, should be also allowed.

Claims 51-53, 55-61, and 63 have been rejected under 35 U.S.C. § 103(a). The Examiner contends that these claims are unpatentable over Weadock in view of Elliot and Baker.

Applicants respectfully traverse this rejection.

As mentioned above, all three cited devices are expandable devices that are inserted through the iliac in shrunk dimensions while Weadock as well as Elliot are expanding towards the vessel and are being fixated to the vessel by their expansion. The fasteners that are engaged after insertion in Weadock are merely facilitating the connection that is already established. The connection between the graft and the vessel in Elliot on the other hand, is not being facilitated by any fastener or engaging members. The devices of Elliot and Weadock are so differentiated so that Weadock's cuffs can not act as a substitute to Elliot's skirt. Moreover, the barbs of Baker are not directed in a predetermined direction and therefore cannot be used in Weadock's or Elliot's device so as to establish the claimed invention device.

The other rejected claims are now dependent on patentable subject matter and therefore, should be also allowed.

Claims 40 and 54 were rejected under 35 U.S.C. § 103(a). The Examiner contends that these claims are unpatentable over Tanner in view of Fogarty et al., U.S. Patent No. 6,110,198 ("Fogarty").

Applicants respectfully traverse this rejection.

Figure 9 in Tanner shows that the cuff is flexible and, therefore, there is no use in placing slits in such a flexible device in order to render flexibility to the device. Fogarty discloses a liner having slits to render flexibility. There is no reason even to a person skilled in the art to combine slits to render flexibility to a device that is already describe to be flexible. Additionally, the slits, described by Fogarty are closed slits (mesh like) in the entire length of the frame structure of the device as opposed to proposed invention, with only one portion containing the open slits, for partial flexibility.

For all of the above reasons, Applicant submits claims that are in proper form and now define patentability and novelty over the prior art. Therefore, the rejections under 35 U.S.C. §§ 102 and 103 should be withdrawn.

In view of the above amendments and remarks it is respectfully submitted that the amended Claims are in condition for allowance. A prompt notice of allowance is respectively and earnestly solicited.

Should the claims be allowable but for minor matters that could be the subject of either an Examiner's Amendment or a supplemental submission by Applicants, Applicants would appreciate the Examiner's contacting Applicants' undersigned attorney.

The amendments to the claims above are limited to slight rearrangement of the language of Claim 37 and the incorporation of the limitation of Claim 44 into Claim 37. These amendments are not intended to raise new issues or to otherwise cause further consideration or searching on the Examiner's part. Therefore, entry of this paper is believed proper and is respectfully requested.

Reconsideration and allowance of the claims herein are respectfully requested.

Respectfully submitted,

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